

William L. Mentlik
Roy H. Wepner
Stephen F. Roth
Aaron S. Eckenthal
LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK, LLP
600 South Avenue West
Westfield, NJ 07090-1497
Tel: 908.654.5000
Fax: 908.654.7866

*Attorneys for Plaintiffs Dr. Reddy's Laboratories,
Inc. and Dr. Reddy's Laboratories, Ltd.*

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

DR. REDDY'S LABORATORIES, INC. and	:	Document Filed Electronically
DR. REDDY'S LABORATORIES LTD,	:	
	:	Civil Action No.
Plaintiffs,	:	
v.	:	District Judge
	:	Magistrate Judge
ASTRAZENECA AB, ASTRAZENECA LP, and	:	
ASTRAZENECA PHARMACEUTICALS LP,	:	
	:	
Defendants.	x	

COMPLAINT AND DEMAND FOR TRIAL BY JURY

Plaintiffs Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (collectively "DRL"), allege the following for their complaint for breach of contract against AstraZeneca AB, AstraZeneca LP, and AstraZeneca Pharmaceuticals LP (collectively "AZ"):

NATURE OF THE SUIT

1. This is a civil action for breach of contract in which DRL seeks pecuniary and injunctive relief from the various acts of AZ arising under the statutory and common laws of New Jersey.

PARTIES

2. Plaintiff Dr. Reddy's Laboratories, Inc. is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 107 College Road East, Princeton, New Jersey 08540.

3. Plaintiff Dr. Reddy's Laboratories, Ltd. is an Indian corporation, with its principal place of business at 8-2-337 Road No. 3, Banjara Hills, Hyderabad, 500 034, Telangana, India.

4. Upon information and belief, Defendant AstraZeneca LP, is a limited partnership operating and existing under the laws of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803.

5. Upon information and belief, Defendant AstraZeneca AB is a company operating and existing under the laws of Sweden, with its principal place of business at SE-151 85 Södertälje, Sweden.

6. Upon information and belief, Defendant AstraZeneca Pharmaceuticals LP is a limited partnership operating and existing under the laws of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803, and is an Affiliate of Defendant AstraZeneca LP and/or AB.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over this matter based upon diversity of citizenship pursuant to 28 U.S.C. § 1332, and the Court's retention of jurisdiction over the parties in the Consent Judgment entered in Civil Action Nos. 3:05-cv-05553 and 3:08-cv-02496. The amount in controversy exceeds \$75,000, exclusive of interest and costs.

8. This Court has personal jurisdiction over AZ, *inter alia*, because AZ has availed itself of the jurisdiction of this Court by initiating litigation in this District, including but not limited to Civil Action Nos. 3:05-cv-05553 and 3:08-cv-02496.

9. Venue is proper in this district pursuant to 28 U.S.C. § 1391(b), as the Settlement Agreement and Consent Judgement entered in Civil Action Nos. 3:05-cv-05553 and 3:08-cv-02496 occurred in this District, and this Court has expressly retained jurisdiction to enforce the Settlement Agreement.

BACKGROUND

10. DRL submitted an Abbreviated New Drug Application (“ANDA”) to the FDA seeking the FDA’s approval to manufacture, use, offer to sell, and sell DRL’s esomeprazole capsules as a generic version of AZ’s NEXIUM® product (ANDA No. 78-279).

11. Subsequent to that ANDA filing, AZ sued DRL for patent infringement (Civil Action No. 3:08-cv-00328-JAP-TJB, later consolidated to 3:05-cv-05553-JAP-TJB), claiming that DRL infringed its drug patents listed for NEXIUM®.

12. During that suit, DRL produced portions of its ANDA and physical samples to AZ, which disclosed the ingredients, form, packaging, and look of its proposed generic product, including that its proposed capsule was purple.

13. The NEXIUM® capsule and the generic equivalent as proposed by DRL in its ANDA and provided to AZ in a physical sample, are shown below with DRL’s proposed capsule on the right.



14. During the litigation with DRL, AZ was made aware and had full knowledge that DRL intended to utilize the color purple for its capsule.

15. In January 2011, AZ and DRL entered into a Settlement Agreement, and on January 28, 2011, this Court later entered an agreed upon Consent Judgement (part of the Settlement Agreement), ending the litigation between AZ and DRL. This Court retained jurisdiction to enforce or supervise the performance under the Settlement Agreement.

16. The Settlement Agreement released DRL from any liability to AZ in connection with DRL's sale of its generic equivalent of NEXIUM as described in DRL's ANDA.

17. To avoid the disclosure of confidential information, an earlier filed motion and supporting brief filed under seal by DRL (Civ. Action No. 05-5553 (D.N.J.) Dkts.301, 303; Civ. Action No. 08-2496 (D.N.J.) Dkts.100, 104), are incorporated herein by reference. Such documents set forth DRL's position as to the legal obligations and effect of the Settlement Agreement between AZ and DRL.

18. On September 25, 2015, DRL commenced the sale of its version of generic NEXIUM® using a two colored purple capsule shown below:



19. About a month after DRL's launch of its generic version of NEXIUM®, AZ filed an action in the District of Delaware (Civil Action No. 1:15-cv-00988-SLR) for, *inter alia*,

trademark infringement for use of a purple colored capsule, and moved for a TRO to preclude the sale of DRL's generic version of NEXIUM®.

20. AZ's motion for a TRO was granted on November 6, 2015, and DRL has been enjoined from selling its generic NEXIUM® since that date.

21. By virtue of the Settlement Agreement, DRL has a right to introduce its generic product as set forth in its ANDA (which includes a purple capsule color) and is released by AZ from claims it had against DRL for its generic NEXIUM®, including the claims for damages and injunctive relief alleged in AZ's complaint against DRL in the District of Delaware.

22. AZ's filing of an action in the District of Delaware is a violation of the Settlement Agreement between the parties.

CLAIM FOR RELIEF
Breach Of Contract

23. DRL repeats and incorporates the preceding allegations as if each were more fully set forth herein.

24. AZ's filing of an action in the District of Delaware for, *inter alia*, trademark infringement, constitutes a material breach of the Settlement Agreement.

25. The specific terms of the Settlement Agreement that AZ has violated are described and set forth in DRL's earlier filed motion and supporting brief (*see* Civ. Action No. 05-5553 (D.N.J.) Dkts.301, 303; Civ. Action No. 08-2496 (D.N.J.) Dkts.100, 104), which were incorporated herein by reference.

26. The aforesaid acts of AZ were committed willfully, knowingly, maliciously, and in conscious disregard of AZ's legal obligations to DRL.

27. The aforesaid conduct of AZ has caused, and unless restrained by this Court will continue to cause, immediate, great, and irreparable harm to DRL's property and business.

28. DRL has no adequate remedy at law.

WHEREFORE, DRL demands judgment as follows:

A. A declaration that AZ has breached the Settlement Agreement as set forth above and directing AZ to cure that breach by, *inter alia*, requiring AZ to dismiss its Delaware Action and request that any injunction against DRL be dissolved;

B. A declaration that, by virtue of the Settlement Agreement, DRL has not infringed any valid and enforceable trademark rights of AZ;

C. An award of compensatory damages arising out of AZ's breach of contract, in an amount to be determined;

D. An award to DRL of its attorney fees and costs;

E. Prejudgment and postjudgment interest on the above monetary awards; and

F. Such other and further relief as this Court deems proper.

JURY DEMAND

Pursuant to Fed. R. Civ. P. 38(b), DRL hereby demands a trial by a jury on all issues so triable.

Respectfully submitted,

LERNER, DAVID, LITTENBERG,

KRUMHOLZ & MENTLIK, LLP

*Attorneys for Plaintiffs Dr. Reddy's Laboratories,
Inc. and Dr. Reddy's Laboratories, Ltd.*

Dated: November 17, 2015

By: s/ William L. Mentlik
William L. Mentlik

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

The undersigned hereby certifies, pursuant to Local Civil Rule 11.2, that with respect to the matter in controversy herein, Plaintiffs and Plaintiffs' attorney are aware of the following proceedings, to which this matter is subject.

- *AstraZeneca AB et al. v. Dr. Reddy's Laboratories, Ltd.*, Civ. Action
No. 3:05-cv-05553-JAP-TJB (previously Civ. Action
No. 3:08-cv-00328-JAP-TJB before consolidation) (D.N.J.)
- *Dr. Reddy's Laboratories, Ltd. et al. v. AstraZeneca AB et al.*, Civ. Action
No. 03:08-cv-02496-JAP-TJB (D.N.J.)
- *AstraZeneca AB et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, Civ. Action
No. 1:15-cv-00988-SLR (D. Del.)

Dated: November 17, 2015

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By: s/ William L. Mentlik
William L. Mentlik
Tel: 908.654.5000
E-mail: wmentlik@lernerdavid.com
litigation@lernerdavid.com